

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

RAVGEN, INC.

Plaintiff,

v.

NATERA, INC. and NSTX, INC.,

Defendants.

Civil Action No.: 1:20-cv-00692-ADA

JURY TRIAL DEMANDED

**DEFENDANTS OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE PORTIONS OF
THE EXPERT DECLARATION OF JOHN QUACKENBUSH, PH.D. (D.I. 49-1)
AND OPPOSED COUNTER-MOTION TO STRIKE PORTIONS OF
DR. GRODY'S EXPERT DECLARATION (D.I. 46-1)**

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TABLE OF EXHIBITS

Exhibits	Description
1	Ravgen's Initial Proposed Claim Constructions
2	Excerpts from Rough Deposition Transcript of Dr. Quackenbush

I. INTRODUCTION

According to Ravgen, Natera was obligated to do the impossible—*predict* that Ravgen would disclose *new* claim construction positions and expert opinions regarding the “agent”¹ term for the first time well after the parties exchanged disclosures of extrinsic evidence on December 3, 2020. After that deadline, Ravgen’s claim construction position morphed from “plain and ordinary meaning” to a tortured and brand-new 54-word construction. Dr. Quackenbush’s opinions related thereto and the various exhibits he cites in support *rebut* Ravgen’s own *new* claim constructions and expert theories it offered *after* the December 3 deadline. Ravgen’s motion to strike exclusively relies on deadline rules where a party does not subsequently disclose new positions, which is not the case here. If either party violated the Court’s scheduling order, it is Ravgen, not Natera. For these reasons—and to avoid unfairly prejudicing Natera—Ravgen’s motion must be denied. In the alternative, to the extent the Court strikes Exhibits 3-16 and paragraphs 21, 23-24, 26-27, 29, 37-38, and 41 from Dr. Quackenbush’s declaration, then paragraphs 19, 35–37, 43-44, 46, 50–53, and 56-59 from Dr. Grody’s declaration must be struck.

II. FACTUAL SUMMARY

Ravgen’s narrative distorts the facts leading up to its motion to strike. Since November 25, 2020, when the parties were first required to disclose their proposed constructions, Natera’s position has been that the “agent” term should be construed as a “[c]ompound that slows or stops cell lysis, including anticoagulants like EDTA (clarification of/consistent with plain and ordinary meaning),” or in the alternative, that it is indefinite. D.I. 53-1 at 2. Natera’s position has never changed. D.I. 53-2 at 7, 11, D.I. 46 at 9, D.I. 49 at 1. Ravgen, however, has changed its claim

¹ The “agent term” refers to the disputed term at issue: “agent that [impedes/inhibits] [cell lysis/lysis of cells/cell lysis to inhibit the lysis of cells] . . . wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker and cell lysis inhibitor.”

construction position at least twice, ultimately settling on a 54-word “plain and ordinary meaning” *after* the December 3, 2020 deadline for disclosure of extrinsic evidence:

- November 25, 2020: Ravgen represented in its initial proposed claim constructions that the agent term should be given its “plain and ordinary meaning.” Ex. 1 at 2.
- December 3, 2020: Ravgen represented in its disclosure of extrinsic evidence that “[t]he plain and ordinary meaning of this claim term [the agent term], as confirmed by the intrinsic record, **would not encompass anticoagulants like EDTA.**”² D.I. 53-3 at 2, 3.
- December 8, 2020: Ravgen represented in a letter that the agent term should be given its “plain and ordinary meaning” or “[i]n the alternative, plain and ordinary meaning, wherein the plain and ordinary meaning is: **‘a substance that inhibits the rupture of cells that is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor, and does not include other categories of substances that only indirectly affect cell lysis such as anticoagulants and chelators like EDTA, nor endogenous substances that are not selected to be added.’**” D.I. 53-4 at 3-4.

Pursuant to the Scheduling Order in place at the time (D.I. 43), the parties were required to disclose extrinsic evidence on December 3, 2020, as follows:

Parties disclose extrinsic evidence. The parties shall disclose any extrinsic evidence, including the identity of any expert witness they may rely upon with respect to claim construction or indefiniteness. With respect to any expert identified, the parties shall identify the scope the topics for the witness’s expected testimony. **[FN 1: Any party may utilize a rebuttal expert in response to a brief where expert testimony is relied upon by the other party.]** With respect to items of extrinsic evidence, the parties shall identify each such item by production number or produce a copy of any such item if not previously produced.

D.I. 43 at 1. Consistent with its claim construction position—and Ravgen’s position at the time—Natera disclosed as its expert Dr. Quackenbush³ to “rebut any expert opinions offered by Ravgen in support of this term” and “confirm that a person of ordinary skill in the art would understand the meaning of this claim term, when viewed in light of the intrinsic and extrinsic evidence, to be consistent with the construction proposed by Natera for this claim term.” Ex. 2 at 7, 11. Ravgen

² Emphasis added unless otherwise noted.

³ Natera also disclosed 10 extrinsic references relevant to Ravgen’s claim construction positions as they existed at the time.

disclosed Dr. Grody’s “*expected* testimony” based on its December 3, 2020 construction (not its December 8 construction) as: “Based on the intrinsic record relating to the ’277 patent, a person of ordinary skill in the art at the time of the invention would understand the scope of this claim term with reasonable certainty. The plain and ordinary meaning of this claim term, as confirmed by the intrinsic record, *would not encompass anticoagulants like EDTA.*”⁴ Ex. 4 at 2-3.

On December 15, 2020, Ravgen filed Dr. Grody’s declaration with its opening brief, which, as discussed *infra*, provided testimony on Ravgen’s latest (December 8, 2020) construction as well as at least four new theories, none of which was identified or even encompassed in Ravgen’s disclosure of extrinsic evidence. D.I. 46, D.I. 46-1. On January 11, 2020, Natera filed Dr. Quackenbush’s declaration, which provided (i) testimony consistent with Natera’s disclosure of extrinsic evidence and (ii) Exhibits 3-16⁵ and testimony related thereto that rebut Ravgen’s latest construction and Dr. Grody’s newly-articulated theories. D.I. 49, D.I. 49-1.

On January 13, 2021, Ravgen notified Natera that it intended to seek relief from the Court. D.I. 53-5. Natera addressed Ravgen’s concerns via its January 15, 2021 letter, explaining in detail how each of Dr. Quackenbush’s opinions rebutted Dr. Grody’s newly-articulated opinions and reserving the right to cross-move if Ravgen persisted in its spurious allegations. D.I. 53-6. On January 18, 2021, Ravgen moved to strike nearly all of Dr. Quackenbush’s declaration. D.I. 53. On January 20, 2021, Ravgen deposed Dr. Quackenbush, questioning him on his declaration, including the paragraphs and exhibits Ravgen is seeking to strike. *See, e.g.*, Ex. 2 at 9:12-11:4, 67:11-14, 86:21-88:16, 92:12-95:15, 99:25-101:18, 110:20-112:23, 143:2-11, 145:22-150:6.

⁴ Ravgen also disclosed one dictionary definition.

⁵ Ravgen quibbles that these exhibits weren’t “produced” until after Natera filed Dr. Quackenbush’s declaration. But Natera emailed these exhibits to Ravgen about 2 hours after Natera filed its brief under seal. D.I. 56-6 at 28 (Ex. C). It is unclear what prejudice, if any, Ravgen suffered.

On January 25, the parties met and conferred regarding Natera's cross-motion, but were unable to resolve the dispute. Pursuant to CV-7(h), Natera requests oral argument on both motions.

III. ARGUMENT

Recognizing that Dr. Quackenbush's rebuttal testimony uses Ravgen's new theories to confirm the "agent" term is indefinite, Ravgen moves to strike Exhibits 3-16 and portions of Dr. Quackenbush's declaration related thereto under the guise that they were not submitted by the extrinsic evidence deadline set by the Court. But Ravgen ignores that these opinions and exhibits were necessitated by Ravgen's modifications of its claim constructions and expert theories after the extrinsic evidence disclosure deadline. Courts have held that while parties should disclose known extrinsic evidence upon which a party intends to rely according to the scheduling order, "this does not extend to the scenario presented here: where a party seeks to produce extrinsic evidence in its . . . claim construction brief to respond to an argument presented for the first time in a party's [opening] claim construction brief." *Parthenon Unified Memory Architecture LLC v. HTC Corp.*, 2015 WL 11117317, at *1 (E.D. Tex. June 4, 2015) (denying motion to strike portions of the expert's declaration that was responsive to newly articulated positions). Courts "expect[] diligence and reasonable foresight in identifying extrinsic evidence, but cannot expect clairvoyance." *Id.* The burden is on the party moving to strike "to show that the producing party has failed to meet that standard." *Id.* Ravgen has failed to meet its burden.

A. Exhibits 3-16 and Dr. Quackenbush's Testimony Related Thereto Rebut Ravgen's Claim Construction and Theories First Disclosed After the Court's Deadline

Well after the parties exchanged extrinsic evidence on December 3, 2020, Ravgen disclosed for the first time new claim construction positions and expert opinions regarding the "agent" term. As discussed above, Ravgen's position drastically changed from the plain and ordinary meaning of the "agent" term (i) "would not encompass anticoagulants like EDTA,"

(December 3, 2020) to (ii) “*a substance that inhibits the rupture of cells* that is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor, and *does not include other categories of substances that only indirectly affect cell lysis such as anticoagulants and chelators* like EDTA, *nor endogenous substances that are not selected to be added*” (December 8, 2020). D.I. 46-23 at 3-4. Ravgen further articulated new theories in Dr. Grody’s declaration (December 15, 2020), explaining that: (i) anti-coagulants are different from cell lysis inhibitors, cross linkers, and membrane stabilizers based on their “functions” and “mechanisms”; (ii) compounds that only “indirectly” inhibit are not cell lysis inhibitors; (iii) compounds within the categories of cell lysis inhibitor, cross linkers, and membrane stabilizers were “well-known” and exclude anti-coagulants; and (iv) percentage of free DNA in blood samples was often too small to render accurate detection or diagnosis. D.I. 46-1 at ¶¶ 35–37, 43, 44, 50–53, 56, 57, and 59. None of the aforementioned theories from Dr. Grody were disclosed in Ravgen’s disclosure of extrinsic evidence. It is for reasons exactly like this—where Ravgen amended its construction and expanded the scope of its expert’s testimony post-disclosure of extrinsic evidence—that *both* parties reserved the right to disclose additional extrinsic evidence, including expert testimony, in response to additional disputes and/or developments in the case. *See* D.I. 53-2 at 1, D.I. 53-3 at 1.

Exhibits 3-16 and Dr. Quackenbush’s testimony related thereto all rebut Ravgen’s amended construction and Dr. Grody’s newly-articulated theories. For example, Dr. Grody argued that “anticoagulants” are an “entirely different category of substances from cell lysis inhibitors, cross-linkers, and membrane stabilizers.” D.I. 46-1 at ¶ 52. He further explained that he believed “[u]nlike the well-known category of cell lysis inhibitors . . . anticoagulants like EDTA . . . perform an entirely different function . . . via a different mechanism.” *Id.* Dr. Quackenbush rebutted Dr. Grody’s testimony, explaining that he “disagree[d],” and cited to exhibits 11–14 to show that

the term cell lysis inhibitor “is not used to distinguish between compounds having a particular ‘mechanism’ of cell-lysis inhibition, or compounds with a particular structural feature.” D.I. 49-1 at ¶¶ 37–38. Similarly, Dr. Grody asserted that compounds only “indirectly” inhibiting cell lysis are not cell lysis inhibitors. D.I. 46-1 at ¶ 59. Dr. Quackenbush rebutted Dr. Grody’s testimony, explaining that this distinction only “creates more confusion” by citing to exhibits 4 and 15, and showing that “indirect” and “direct” inhibition could not be applied to cell lysis. D.I. 49-1 at ¶¶ 42–43. As shown below, Exhibits 3-16 and Dr. Quackenbush’s testimony related thereto all rebut Ravgen and Dr. Grody’s new claim construction position and theories.

Dr. Grody’s Declaration	Dr. Quackenbush’s Declaration
Testified that anti-coagulants are different from cell lysis inhibitors, cross linkers, and membrane stabilizers based on their “functions” and “mechanisms.” D.I. 46-1 at ¶¶ 37, 43, 44, 46, 50–53, 56, 57, 58.	Exhibits 4-14 and paragraphs 23–24, 26–27, 29, and 37–38. from Dr. Quackenbush’s declaration discuss cell-lysis mechanisms of formaldehyde, EDTA, and other cell-lysis inhibitors.
Testified that compounds within the categories of cell lysis inhibitor, cross linkers, and membrane stabilizers were “well-known” and exclude anti-coagulants. <i>Id.</i> at ¶¶ 35–37, 43, 44, 46, 50–52, 56, 58.	Exhibits 11-14 and paragraphs 23, 26, 29, and 37–38 from Dr. Quackenbush’s testimony related thereto explain that anti-coagulants are cell lysis inhibitors.
Testified that compounds that only “indirectly” inhibit are not cell lysis inhibitors. <i>Id.</i> at ¶¶ 37, 59.	Exhibits 4 and 15 and paragraph 41 from Dr. Quackenbush’s declaration explain that direct versus indirect inhibition is not a meaningful distinction and that inhibitors of both pathways are considered cell lysis inhibitors.
Testified that the percentage of free DNA in blood samples was often too small to render accurate detection or diagnosis. <i>Id.</i> at ¶ 19.	Exhibits 3 and 16 and paragraph 21 from Dr. Quackenbush’s declaration explain that the percentage of free DNA in blood samples was sufficient for accurate detection.

Ravgen fails to address any of this. Instead, Ravgen quibbles that Natera should have disclosed its “updated extrinsic evidence” under the “updated proposed Scheduling Order” filed on December 17, 2020. D.I. 47 at 1. Not true. The updated scheduling order, which was revised to accommodate Ravgen’s late assertion of new claims against Natera, required both parties to

disclose extrinsic evidence on December 23, 2020 for the *new* claim terms asserted, not the original claims that already included the “agent” term. *Id.* As such, neither party disclosed any extrinsic evidence that day.

Ravgen further quibbles that “Defendants should not be heard to argue that new extrinsic evidence was required to respond to Dr. Grody’s opinion because Dr. Grody only relied on previously identified materials to support his opinions.” D.I. 53 at 5. Ravgen misses the point. Ravgen subsequently and drastically altered its construction and the content of its expert’s testimony after the December 3 extrinsic evidence deadline. Ravgen should not be permitted to repeatedly alter its own claim construction positions and theories after the relevant deadlines, while simultaneously denying Natera the opportunity to respond to its new and unexpected positions. Moreover, under the express language of the Scheduling Order, Natera would be entitled to rebut Ravgen’s testimony with its own expert testimony, *even if Natera had not previously identified any expert opinions at all.* D.I. 43 at n.1.

B. To the Extent the Court Determines that Natera’s Disclosure was Untimely—Which is not the Case—Its Delay was Both Justified and Harmless

As discussed above, Exhibits 3-16 and Dr. Quackenbush’s testimony related thereto rebut Ravgen’s and Dr. Grody’s newly disclosed theories. As such, the four-factor test⁶ used by the Fifth Circuit to determine whether a delay in disclosing evidence was (i) substantially justified or (ii) harmless is not relevant to the instant circumstances. Nonetheless, to the extent the Court

⁶ The four factors articulated by the Fifth Circuit are: “(1) the explanation for the failure to identify [the evidence]; (2) the importance of the testimony; (3) potential prejudice in allowing the testimony; and (4) the availability of a continuance to cure such prejudice.” *Pisony v. Commando Constructions, Inc.*, 2020 WL 4934463, at *2 (W.D. Tex. Aug. 24, 2020) (citing *Certain Underwriters at Lloyd's v. Axon Pressure Prods. Inc.*, 951 F.3d 248, 270 (5th Cir. 2020)).

determines that Natera untimely disclosed Exhibits 3-16 and Dr. Quackenbush's related testimony, Natera's delay was both justified and harmless.

First, as explained above, Natera could not have foreseen that Ravgen would disclose new claim construction positions and expert theories after the December 3, 2020 deadline (Factor 1). And for Ravgen to contend that Natera should have done so on then non-existent Ravgen theories is manifestly unreasonable.

Second, Exhibits 3-16 and Dr. Quackenbush's testimony related thereto are critical to show the fallacies in Ravgen's new claim construction positions and theories, including how Ravgen's new positions further render the "agent" term indefinite (Factor 2). *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 2008 WL 7328271, at *10 (W.D. Tex. Sept. 30, 2008) (denying the motion to strike because the expert declaration was relevant to the indefiniteness inquiry). Ravgen's assertion that Dr. Quackenbush's testimony relating to Exhibits 3-16 is not important because Natera does not cite to it in its responsive claim construction brief is categorically false.⁷ *See, e.g.*, D.I. 49 at 7, 11 (citing paragraphs 26 and 37-38 from Dr. Quackenbush's declaration).

Last, Natera would be severely prejudiced if Ravgen and Dr. Grody were allowed to disclose new claim constructions and theories but Natera is not allowed to rebut them (Factor 3).⁸ Ravgen's claim that it "was substantially prejudiced by [Defendant's] delay because it handicapped Ravgen's ability to understand and address Defendant's claim construction positions" is pure fiction. Not only

⁷ Indeed, Ravgen's extraordinary effort to exclude Exhibits 3-16 and Dr. Quackenbush's testimony related thereto itself shows that they are important, and relevant, to Natera's case.

⁸ That extrinsic evidence may be "less significant" than intrinsic evidence, as Ravgen contends, does not justify preventing Dr. Quackenbush's testimony from being heard. *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1346 (Fed. Cir. 2003). Claim construction is a matter for the Court, so the Court will ultimately decide what weight the extrinsic evidence should get. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Accordingly, there is no prejudice that demands striking Exhibits 3-16 or Dr. Quackenbush's related testimony.

has Natera’s claim construction for the “agent” term not changed once throughout this entire case, but Ravgen had a full 7 hours to depose Dr. Quackenbush on his opinions last week. Ravgen only took about 5 hours and 47 minutes of that time, questioning him on many of his opinions, including those Ravgen is seeking to strike. *See supra* at pg. 3. Ravgen has its upcoming reply brief,⁹ as well as the *Markman* hearing, in which to address Dr. Quackenbush’s testimony.¹⁰ As such, Ravgen’s perceived prejudice is unfounded—indeed, it is belied by Ravgen’s own actions in this litigation. *Betzel v. State Farm Lloyds*, 480 F.3d 704, 709 (5th Cir. 2007) (finding district court abused its discretion in striking an expert report when it was at “the extreme end of the sanction spectrum . . . imposed against the lowest end of the prejudice spectrum”).

C. Ravgen’s Red Herrings are Not Relevant to its Motion to Strike and Should be Disregarded

Ravgen’s motion contains numerous red herrings unrelated to the basis for its motion, such as the narrowing of unrelated, disputed claim terms. *None* of this is relevant to whether certain portions of Dr. Quackenbush’s declaration relating to the “agent” term should be struck. For example, Ravgen complains that it was “prejudiced” because Natera dropped the previously disputed terms “sample” and “determining the sequence [of alleles] [at the/of a] locus of interest” (the “determining” term) from its responsive claim construction brief and changed its construction of the term “relative amount of [the] alleles.” As Ravgen well-knows, Natera dropped the “sample” and “determining” terms in an effort to narrow claim construction issues and narrowed

⁹ While Ravgen contends that Natera declined to agree to a page limit extension for Ravgen’s reply, Ravgen was seeking at least a 6-page extension for the two terms Natera dropped and the one term Natera narrowed—not for any alleged prejudice regarding the “agent” term. *See* Section C. Moreover, it is not up to Natera to extend page limits established by the Court. Ravgen had ample opportunity to request additional pages from the Court, but chose not to.

¹⁰ Since both parties will depose each other’s experts and address each other’s positions in the reply/sur-reply briefing and at the *Markman* hearing, no continuance is necessary (Factor 4).

its construction of “relative amount of [the] alleles” because it was clear from Plaintiff’s opening claim construction brief that they failed to understand the crux of the disputed claim scope. D.I. 53-6 at 4. Ravgen’s attempt to confound the dispute before the Court should be ignored.

D. To the Extent the Court Strikes Portions of Dr. Quackenbush’s Declaration, Portions of Dr. Grody’s Testimony Should also be Struck

Natera has not violated the Court’s scheduling order. But to the extent the Court deems otherwise, and finds that such failure was neither justifiable or harmless, then so too is Ravgen’s untimely disclosure of its current claim construction positions and theories, as disclosed in paragraphs 19, 35–37, 43-44, 46, 50–53, and 56–59 in Dr. Grody’s declaration. Ravgen has failed to provide *any* explanation for its untimely disclosure (Factor 1). *Betzel*, 480 F.3d at 707 (holding that “exclusion of expert [testimony] is particularly appropriate where the party has failed to provide an adequate explanation. . . .”). And as discussed above, Natera would be prejudiced if Ravgen and Dr. Grody were allowed to disclose new claim construction theories, and Natera were not allowed to rebut them (Factor 3). If, as Ravgen contends, Dr. Quackenbush’s opinions are not important because they are trumped by the intrinsic record, then under the same logic, Dr. Grody’s opinions are equally as unimportant (Factor 2). While, no continuance is necessary given that both parties have the opportunity to depose each other’s experts and address any testimony in their reply and sur-reply briefing as well as at the *Markman* hearing (Factor 4), the factors weigh in favor of striking Dr. Grody’s testimony, if portions of Dr. Quackenbush’s testimony also are struck.

IV. CONCLUSION

For the foregoing reasons, Natera respectfully requests that the Court deny Ravgen’s motion to strike. To the extent the Court strikes portions of Dr. Quackenbush’s declaration, however, Natera respectfully requests that the Court also strike paragraphs 19, 35–37, 43-44, 46, 50–53, and 56–59 from Dr. Grody’s declaration.

Dated: January 25, 2021

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

The undersigned counsel certifies that counsel for the parties conferred on January 25, 2021 in a good faith attempt to resolve the matters at issue in this response and cross-motion. Plaintiff's counsel did not agree to withdraw paragraphs 19, 35–37, 43, 44, 46, 50–53, and 56–59 of the Expert Declaration of Dr. Wayne Grody, Ph.D (D.I. 46-1). Thus, the foregoing cross-motion is necessary and opposed.

/s/ Stephen M. Hash
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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record are being served this 25th day of January 2021,
with a copy of this document via the Court's ECF system.

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